

**REMARKS/ARGUMENTS**

**Introduction/Summary**

In the specification, the paragraphs [0042] and [0050] have been amended to correct minor informalities. Applicant understood during the June 29<sup>th</sup> interview that the instant amendments to the specification overcame the objection.

The Examiner required the following changes to the drawings: "...figure 2 includes reference character 118, referring in the specification to "circular lip" comprising notches 122 and 124 (page 13, par. 42), however figure 2 is missing character "122" and it appears that character 118 is pointing to a notch."

By this amendment Applicant has made the amendments to the drawings in compliance with the above referenced Examiner's requirement. The changed drawings are set forth in the Appendix A. Entry is requested. Applicant understood during the June 29<sup>th</sup> interview that the instant amendments to the drawings overcame the objection.

Claim 11 is amended by this amendment. Claims 14 – 16 are rewritten as Claims 32-35, in independent form, embodying all limitations contained in the claims upon which they are dependent, and, therefore, are believed allowable. Claim 26 has been amended to correct the oversight and the term "notches" is now specified. Claims 26 – 31 are now believed in condition for allowance. Applicant understood during the June 29<sup>th</sup> interview that the instant amendments to claim 26 overcame the objection.

As originally filed, the present application presented claims 1 through 31 for examination. Claims 1 through 31 were subject to a restriction requirement under 35 U.S.C. § 121 as follows:

- I. Claims 1-10 and 17-25 drawn to apparatus, classified in class 606, subclass 139.
- II. Claims 11-16 and 26-31 drawn to method of using, classified in class 606, subclass 139.

In Applicant's previous response to Restrictions Requirements, in the conclusionary statement, election of Claims 26 – 31 was inadvertently denoted as 18 - 31, and, further, in the Office Action, this error was recited by the Examiner and, in addition, Claim 10 was inadvertently omitted. Therefore, the correct designation of elected species is Claims 11-16 and Claims 26 – 31. Non-elected species are Claims 1-10 and 17 -25. This error was brought

to the Examiner's attention during the interview. Correction on the record is respectfully requested.

**Rejection – 35 USC §112**

The Examiner rejected Claim 26 under 35 USC §112, second paragraph, "... as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." Specifically, the Examiner stated that, "Claim 26 recites the limitation "the notches" in line 6. There is insufficient antecedent basis for this limitation in the claim." The claim has been amended to affirmatively recite this element without need for antecedent basis. Removal of this rejection in light of the amendment is respectfully requested. It was understood during the June 29<sup>th</sup> interview that this amendment overcame the rejection.

**Claim Rejections – 35 USC §103**

The Examiner rejected Claims 11-13 under 35 USC §103(a) as being unpatentable over Schoeller et al. in view of Kohl (US 2,973,761). Specifically, the Examiner stated that,

"Schoeller teaches a method of abdominal surgery comprising circum dissecting the umbilicus, but does not teach wherein the umbilicus is protected by being enveloped within an open ended vessel. Kohl teaches an open-ended tubular element 10(a) for drawing in an umbilical pedicle (u) into the interior of the vessel (fig. 6) in order to protect the umbilicus." (Emphasis added)

First, independent Claim 11 has been amended by this amendment to more particularly point out Applicant's invention. Specifically, Claim 11 has been amended to recite that the abdominal surgery is subcutaneous. Antecedence is found throughout the specification and, for example, in the "**Field of the Invention:** this invention is directed to "a device for protecting the umbilicus during abdominal subcutaneous surgery." This further distinguishes Kohl. In addition, Claim 11 now recites that the device is adapted for enveloping the umbilicus and umbilical pedicle within the an open ended vessel proximate the distal end of the vessel to protect the umbilical and the umbilical pedicle during the surgery. Enveloping is to "...retain the entire stalk of umbilicus 44 down to the abdominal fascia 56 within housing 16", as set forth in the specification. This further distinguishes Kohl in that Kohl uses a split vessel in which the whole of the vessel is used to surround an umbilical cord (not a pedicle) to keep the cord from kinking (a wholly different purpose).

### The References

Schoeller is cited as teaching a method of abdominal surgery comprising circum dissecting the umbilicus. However, the Examiner completely ignores the teaching of this reference. The title “New Technique for Scarless Umbilical Reinsertion in Abdominoplasty Procedures” telegraphs the substance of the article which relates to the goal of abdominoplasty in emphasizing the restoration of the umbilicus to its most natural form, i.e. a cone shaped orifice. In accordance with the method, “disfiguring results can be avoided by using the original umbilicus as a framework for the new umbilicus created from the skin of the abdominal flap, thus avoiding paraumbilical incisions,” by use of “... this new operative technique (which) results in a more natural appearing umbilicus after abdominoplasty procedures.” The procedure involves, “... splitting the umbilical stalk at the 6 o’clock position from its rim through the crater bottom along the neck down to the fascia (see Figure 4).”

Thus, this reference teaches a procedure that is not possible in accordance with the claimed method of the instant invention, since the umbilical stalk from its “rim through the crater bottom” is not accessible to be split, because the tubular member element of the claimed method covers this portion. Further, this procedure has nothing to do with protecting the umbilical stalk, but in fact involves presenting a thin skinned cone shaped abdominal flap to create a skin crater to more clearly esthetically represent a natural naval. There is nothing to suggest in this reference protection of the umbilical stalk during subcutaneous abdominal surgery and, in fact, this reference teaches directly away from the use of such protection. The Examiner pointed to the sutures during the interview. These sutures are standard closing sutures used to secure the skin flap to the pedicle for healing, not “tacking” sutures.

Kohl is then cited in combination with Schoeller as teaching an “open-ended tubular element 10(a) for drawing in an umbilical pedicle (u) into the interior of the vessel (fig. 6) in order to protect the umbilicus.”

First, the Examiner agreed during the interview that Kohl relates to “umbilical cords” only and not “umbilical pedicles.” Specifically, Kohl recites “u” as an umbilical cord. For example, “In order to jack the tubular protector sheath 10 onto the umbilical cord “u” gripped in the clamp means, special guide means, including slit spreader and sheath retainer means, are provided on the applicator” (col. 4 lines 3-6) and “One stretch of the umbilical cord “u” is gripped and held in the clamp means 12h, 12i. (col. 4 lines 70-72). Also see Figures 5 and 6.

As set forth in the interview, Applicant would respectfully bring to the Examiner's attention that Kohl does not teach or for that matter even mentions an "umbilical pedicle." The Examiner acknowledges that adults and even babies right after they are born no longer have umbilical cords and that an umbilical pedicle and an umbilical cord are not the same. Therefore, the Examiner's assertion that, Kohl discloses a method of drawing an umbilical pedicle U into the interior of the vessel (fig. 6) in order to protect the umbilicus is incorrect.

Second, the reference relates to obstetrical instruments and, more particularly, concerns new and improved means for safeguarding an infant during childbirth against injury or death caused by compression of the umbilical cord. (col lines 15-19). This is to protect a newborn from the detrimental affects of compression (strangulation) of the umbilical cord during difficult births. This is in no way designed to act as a shield or protection of the cord itself, and, most certainly, not the umbilical pedicle.

Finally, the Examiner's characterization of Kohl as disclosing that the umbilical pedicle is "drawn into the interior of the vessel," is also an incorrect reading of Kohl. An umbilical cord is attached both to the baby on one end and the placenta within the mother on the other. Thus, the casing or vessel of Kohl must be split. Specifically, at col. 2, line 10, it is disclosed that,

"The improved umbilical cord protector comprises an elongated resiliently flexible round tubular sheath having a longitudinal slit therein and sufficient wall flexibility to permit spreading apart the sides thereof of the slit for application to the umbilical cord, resilience of the walls causing them to reclose around the cord and stiffness of the walls preventing crushing of the cord."

In fact, Figure 6, referenced by the Examiner, actually shows that the cord is not "drawn" into the tube, but is in fact placed therein through a slit. An applicator instrument or jack, as shown in Figure 2, is required to spread the tube for placing the umbilical cord therein. This does not relate to drawing an umbilical pedicle into a vessel, as suggested by the Examiner. Even though, the application of this prior art is not applicable to the claims as originally filed, Claim 11 has been amended to more specifically indicate that the enveloping of the umbilical and the umbilical pedicle within the vessel is proximate the distal end of the vessel. This is not taught, intimated nor possible with Kohl.

It is therefore respectfully submitted that the Examiner has failed to meet the burden of proof of establishing a *prima fascia* case of obviousness as required by the statutes,

regulations and case law. Specifically, it is the burden of the U.S. Patent and Trademark Office to establish a *prima facie* case of obviousness by “substantial objective” evidence.

To establish a *prima facie* case of obviousness, the U.S. Patent and Trademark Office must meet three basic criteria. First, the prior art reference (or references when combined), considered as a whole, must teach or suggest all the claimed limitations. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, without the benefit of hindsight afforded by the claimed invention, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success. *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n. 5, 229 U.S.P.Q. 182, 187, n. 5 (Fed. Cir. 1986), MPEP 2141.

As set forth above, the references cited by the Examiner, either alone or in any combination, do not yield all of the elements of Applicant’s claimed method, either as originally filed or amended. No reading of Schoeller allows the combination of the disclosed method with any manner of umbilical pedicle protection, much less that claimed by Applicant. The requirement to split the pedicle stalk is precluded by Applicant’s protective method. Likewise, no reading of Kohl yields the teachings attributed to this reference by the Examiner. This reference relates to obstetrics and involves a method of preventing kinking or cramping of an attached umbilical cord during problematic births. Kohl is specifically directed to a device, not a method, for retaining the umbilical cord during birth during prolapse or breach birth cases (Col. 1, lines 48 and 49). Specifically, the device of Kohl is for safeguarding the infant during child birth by prevention compression of the umbilical cord. This device has absolutely nothing to do with protection of the umbilical pedicle during subcutaneous abdominal surgery.

Moreover, it is respectfully submitted that it is Examiner’s burden to specifically show “substantial evidence” that the reference teaches every claimed aspect of the claimed invention. *In re Sang Su Lee* 277 F.3d 1338; 2002 U.S. App. LEXIS 855; 61 U.S.P.Q.2D (BNA) 1430 (2002). Mere conclusionary statements will not suffice. *In re Zurko*, 258 F.3d 1379 (Fed. Cir. 2001). It is respectfully submitted that Applicant has demonstrated that the statements of the Examiner regarding the individual references, as well as their combination, are conclusionary on her part and do not objectively recite the teachings of these references, either singularly or in combination. Therefore, the Examiner has not met the first element.

Further, it is improper for the Examiner to use hindsight determination in the piecemeal application of references to attempt to yield Applicant's invention. It is respectfully submitted that based upon the references and the Examiner's recitation of their teaching, that the Examiner has read the Applicant's specification and then tried to force fit these unrelated references into Applicant's claimed method by a mischaracterization and misreading of the teachings. Therefore, the Examiner has failed to meet the second element.

Finally, there must be a reasonable expectation of success in combining the references cited. It is already been carefully pointed out that Schoeller cannot be used with any vessel protection device and that Kohl relates to protection of children from cramped or kinked umbilical cords. Kohl involves enveloping an umbilical cord in a split tube to prevent oxygen starvation of the baby during difficult births. There can be no expectation of success in combining the two references in any manner, in that they are totally unrelated and inoperative to yield the claimed method. Therefore, the Examiner has failed to meet the third element.

For the above reasons, the Schoeller and/or Kohl references cannot form the basis for an obviousness rejection of Claims 11 - 13 as amended. Applicant understood during the June 29<sup>th</sup> interview that the instant arguments and clarifying amendments to the claim overcame the rejection over the art of record.

#### **Allowable Subject Matter**

Claims 14-16 and 27-31 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claims. Claims 14 – 16 are rewritten in independent form as new Claims 32-35 embodying all limitations contained in the claims upon which they are dependent, and therefore are believed allowable. Claim 26 has been amended to correct the oversight and the term “notches” is now specified. Claims 26 – 31 are now believed in condition for allowance. Applicant understood during the June 29<sup>th</sup> interview that the instant claims as rewritten in independent form overcame the rejection.

#### **Conclusion**

Based upon agreements reached by Applicant's attorney and the Examiner in the June 29<sup>th</sup> interview, the instant arguments and clarifying amendments to the claims overcame the

rejection over the art of record; and, the amendments to the specification and the drawings overcame the objections thereto. No new matter has been added by this amendment

Paragraphs [0042] and [0050] have been amended to correct minor informalities. The drawings have been amended in compliance with the Examiner's objection. The changed drawings are set forth in the Appendix A. Entry is requested.

Claim 11 is amended by this amendment to further distinguish from the cited art. Antecedent basis is found in the specification as filed. It is believed allowable over the prior art of record for reasons set forth above. Claims 14 – 16 are rewritten in independent form as Claims 32-35, embodying all limitations contained in the claims upon which they are dependent, and therefore are believed allowable. Claim 26 has been amended to correct the oversight and the term “notches” is now specified. Claims 26 – 31 are now believed in condition for allowance.

If the Examiner has any questions, Applicant requests that the Examiner telephone the undersigned.

Applicant believes that no fees are due with respect to this paper.

Respectfully submitted,

Date: July 18, 2006

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# *Drawings Showing Corrections*

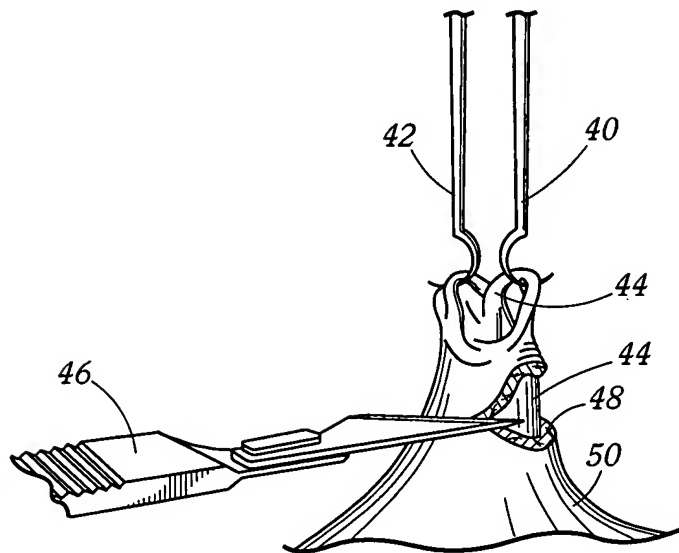


FIG. 4

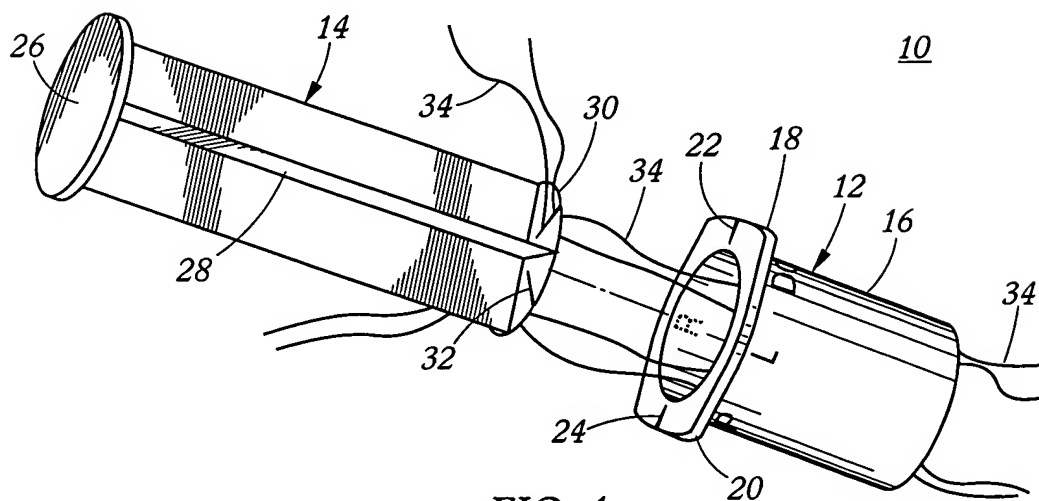


FIG. 1

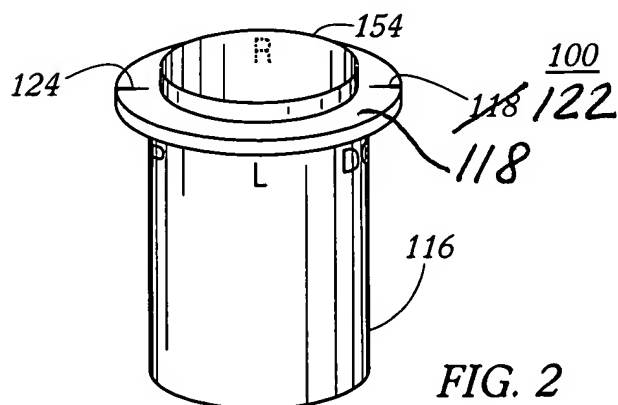


FIG. 2